Review of the California Ambient Air Quality Standard for Ozone

Air Resources Board

Office of Environmental Health Hazard Assessment

California Environmental Protection Agency

Introduction

- Purpose of this meeting
- AQAC members:
  - Roster
  - Expertise
- Meeting logistics
- Agenda

Overview

- What is an ambient air quality standard?
- The Children's Environmental Health Protection Act (SB25, Escutia, 1999)
- Standard setting in California
- Role of AQAC
- Timeline for the ozone standard review
- Recommended ozone standard
- The staff report and recommendations

What Is An Ambient Air Quality Standard?-1

- Legal definition of clean air
- Elements
  - Definition of the pollutant
  - Averaging time
  - Concentration
  - Monitoring method
- Provide a basis for preventing or abating adverse health effects

What Is An Ambient Air Quality Standard?-2

- Highest pollutant concentration for a given averaging time that is **unlikely** to induce adverse effects in **anyone** who undergoes the defined exposure
- Incorporate a “margin of safety” in consideration of potentially sensitive people who were not included in studies
- Likelihood of exposure is not a consideration

The Children's Environmental Health Protection Act (SB25 Escutia, 1999)

- Preliminary review of the adequacy of all CA ambient air quality standards
- Emphasized effects on infants and children
- Prioritization of standards found possibly inadequately protective - completed in 2000

Results of 2000 AAQS Prioritization Process

1st Priority Pollutant	Review Schedule
PM10 (including sulfates)	2002
Ozone	2005
Nitrogen dioxide	2005

Adapted from Staff Report Entitled “Adequacy of CA Ambient Air Quality Standards: Children’s Environmental Health Protection Act,” December 2000.

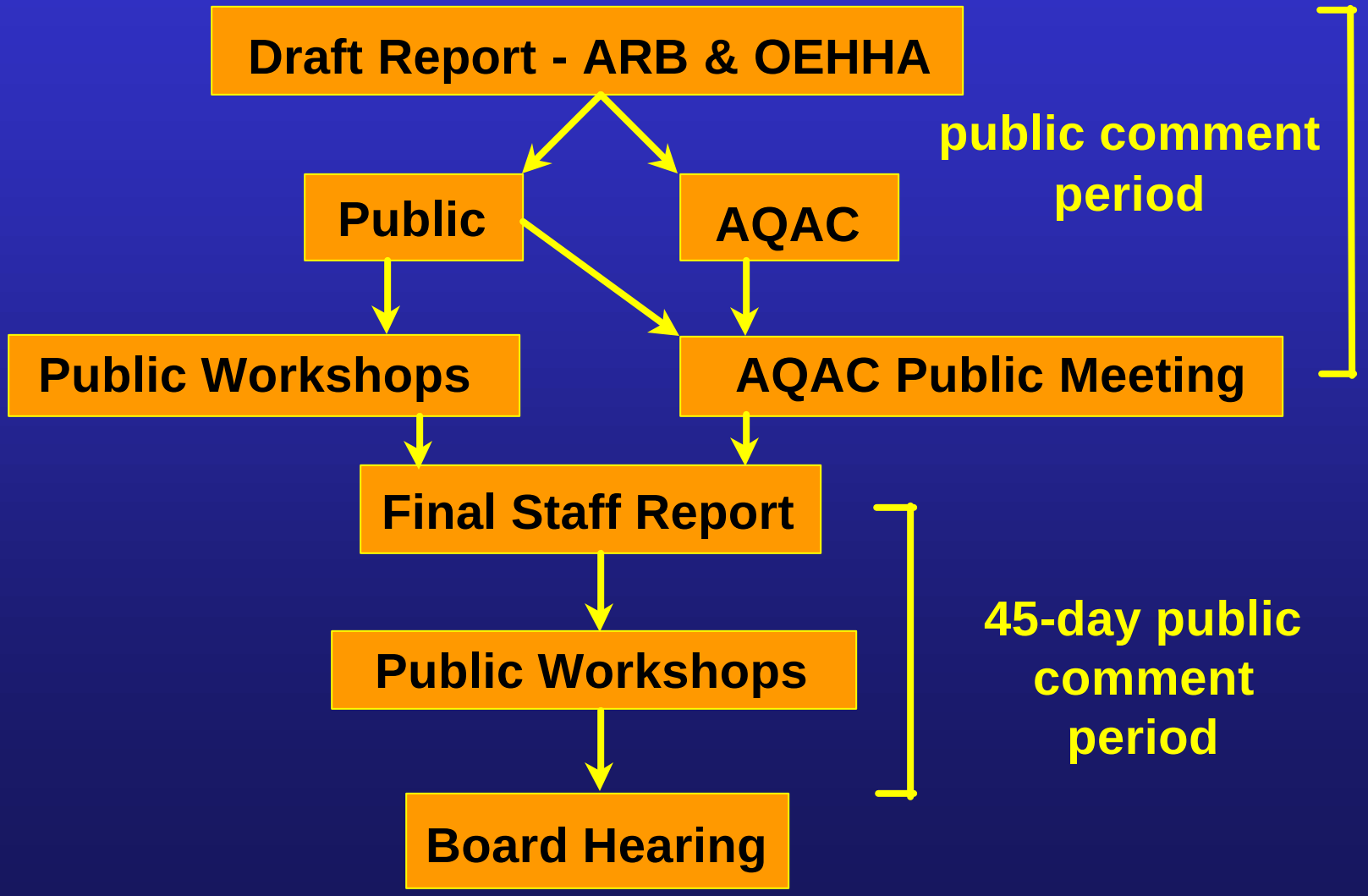
Why Are We Concerned about Ozone?

- Health effects are significant
- Body of evidence is substantial
- Exposure is high in California
- Children may be particularly vulnerable

CA Standard-Setting Process

- Federal Clean Air Act gives CA authority to set its own air quality standards
- Federal law does not apply to State regulations
- Standard setting process follows requirements of:
  - CA Health & Safety Code
  - CA Administrative Procedure Act

What are the Regulatory Steps in a Standard Review?



The Role of AQAC

- H&SC §39606 (C) - Requires peer review of the scientific basis of the staff report and recommendations
- AQAC peer review process:
  - Review staff report and recommendations at a public meeting
  - Consider public comments on the report and recommendations
  - Prepare a written evaluation of the report and recommendations

Timeline for Ozone Review

June 21, 2004	Release of Draft Report
July-August 2004	Public Workshops
January 11-12, 2005	AQAC meeting
April 2005	Final recommendations to Board (tentative)

The Ozone Standard Review Document

- Physics and chemistry of ozone
- Background ozone in California
- Ozone precursor sources and emissions
- Monitoring method
- Characterization of statewide ozone concentrations
- Welfare effects: forests, agriculture, materials
- Health effects
- Quantification of the health effects of ozone

Current California Ambient Air Quality Standard for Ozone

- Definition of the pollutant: ozone
- Averaging time: 1 hour
- Concentration: 0.09 ppm
- Monitoring method: ultraviolet absorption

Recommended Ambient Air Quality Standards for Ozone

- Definition of the pollutant: ozone
- Averaging times and concentrations:
  - One hour average: 0.09 ppm
  - Eight hour average: 0.070 ppm
- Monitoring method: ultraviolet absorption

Recommendation for an Ambient Ozone Air Quality Standard

Bart Ostro, Ph.D.

Melanie Marty, Ph.D.

Shelley Green, Ph.D.

Office of Environmental
Health Hazard Assessment

California Environmental Protection Agency

Draft Recommendation to Revise the California Ozone Standard

- Retain ozone as the pollutant definition
- Establish a new 8-hr standard of 0.070 ppm, not to be exceeded
- Retain the current 1-hr standard of 0.09 ppm, not to be exceeded
- Retain the UV monitoring method

Evidence on the Health Effects of Ozone Provided from Hundreds of Studies

- Human chamber
- Animal toxicology
- Epidemiology

American Thoracic Society Criteria for Adverse Air Pollution Effect

- Physiologic or pathologic change that interferes with normal activity
- Episodic or incapacitating respiratory illness
- Permanent and/or progressive respiratory injury/dysfunction.
- Reduction in quality of life
- Lung function changes with concurrent symptoms
- Hospitalization or emergency room visits
- Mortality
- Population health in addition to individual risk

Inhaled Dose is Important

- Acute health response related to Inhaled Dose = ozone concentration X ventilation rate X exposure duration
- Concentration appears most important
- Controlled study protocols mimic exposures of those thought to be a greatest risk: children & adults who exercise or work outdoors

Controlled Human Studies (1-3 Hour Exposure): Lowest Concentrations Showing Effects

- Lung Function Decrements: 0.12 ppm (not 0.10 ppm)
- Increased Respiratory Symptoms: 0.12 ppm (not 0.10 ppm) (cough at 0.12 ppm; PDI and SB at 0.24 ppm)
- Increased Airway Resistance: 0.18 ppm
- Airway Inflammation: 0.20 ppm

Controlled Human Studies (6.6-8 Hour Exposure): Lowest Concentrations Showing Effects

- Lung function decrements: 0.08 ppm
- Increased respiratory symptoms: 0.08 ppm.
- Increased airway reactivity: 0.08 ppm.
- Airway inflammation: 0.08 ppm.
- No group-level effect at 0.06 and 0.04 ppm

FEV1 response changes with length of exposure

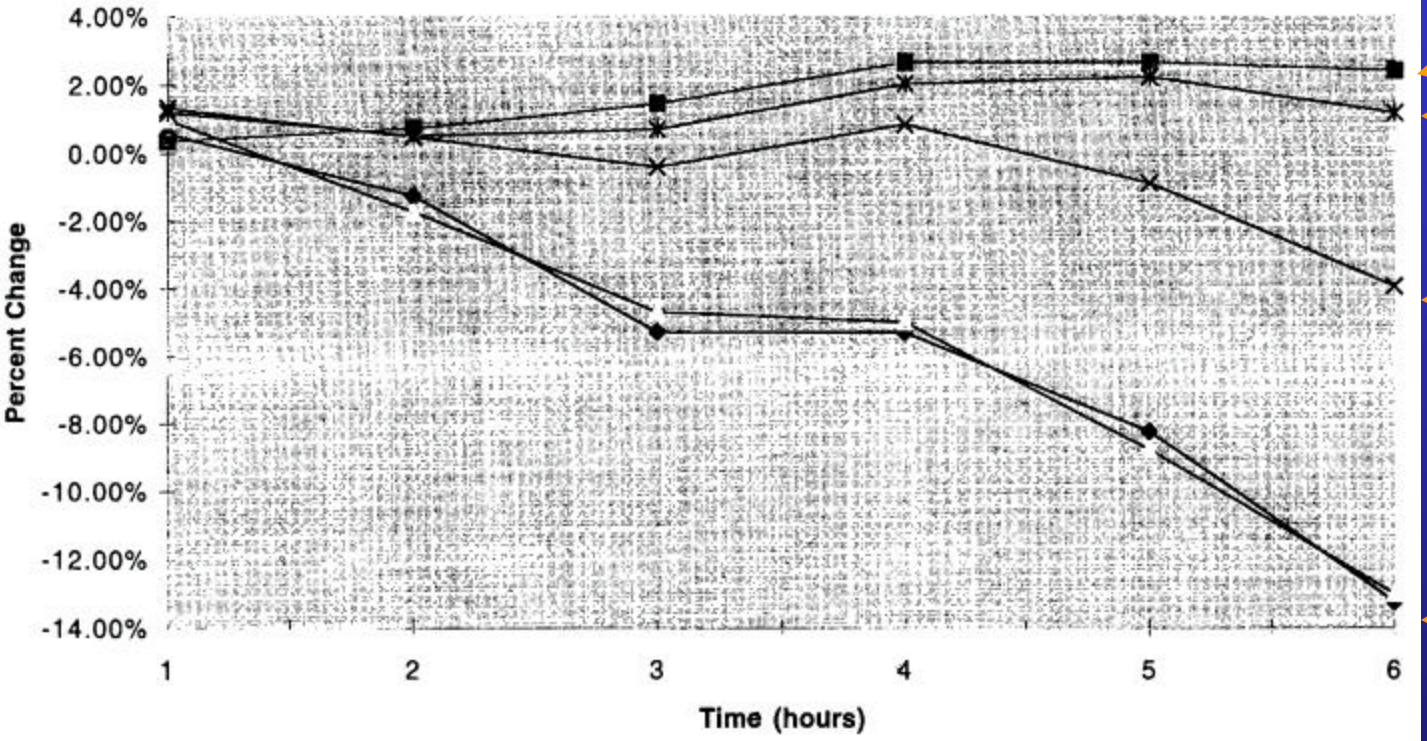


FIGURE 1. Hour-by-hour percent change in $FEV_{1.0}$.

Clean air

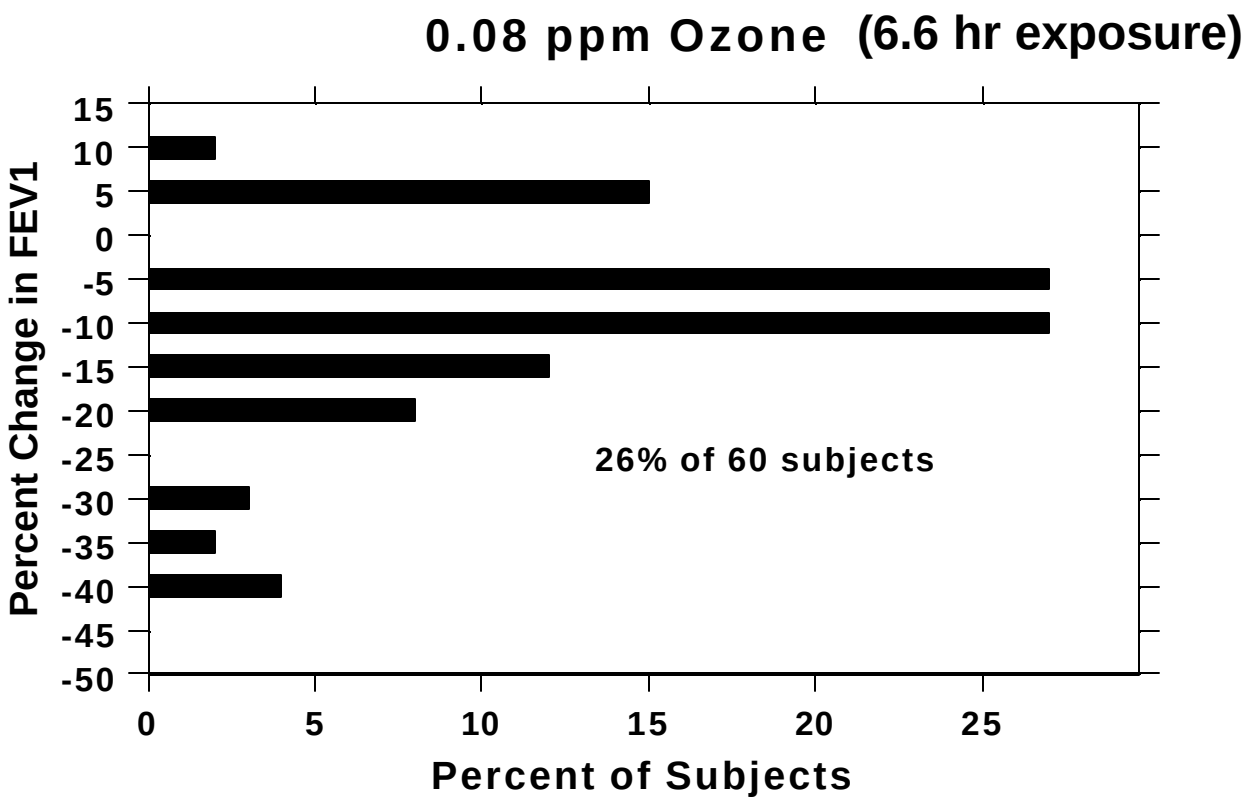
0.04 ppm

0.08 ppm

0.12 ppm

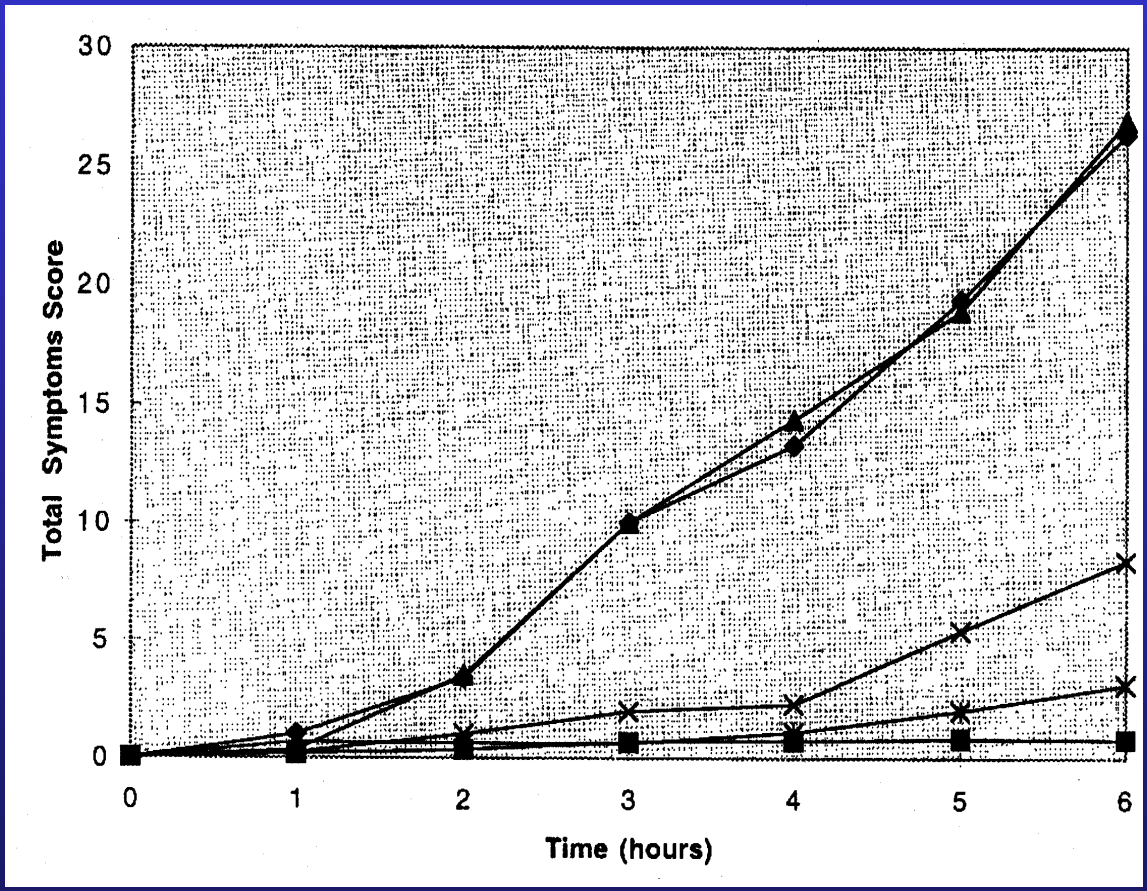
Source: Adams (2002)

Some Individuals May Be Particularly Responsive



Folinsbee et al., 1991

Change in Respiratory Symptoms with Length of Exposure



0.12 ppm

0.08 ppm

0.04 ppm

Clean air

Hour-by-hour change in total symptoms score

Adams, 2002

Additional Considerations

- Some reduction in response (FEV1 and symptoms) after multi-day fixed exposures but:
  - No attenuation for some individuals
  - Possible increase in response with higher exposure
  - Inflammation may continue
- Evidence of repeated response after 4 - 7 days of low exposure
- Individual response usually replicable
- Difficult to predict responders

Influence of Demographics on Responsiveness

- Few studies conducted
- Factors Investigated
  - Gender
  - Age
  - Socioeconomic Status
  - Race
- Insufficient data to draw conclusions

Animal Studies Generally Support Human Studies

- Demonstrate increased airway resistance and airway inflammation at low levels
- Repeated injury-repair cycles can cause fibrosis
- Changes in airway architecture with chronic exposure to high O_3 concentrations (> 0.20)

Epidemiological Studies provide Additional Basis for Margin of Safety

- Examine “real world” exposure conditions, potentially more vulnerable populations, varied endpoints, lags and long-term exposures
- Uncertainty about relevant exposure average, time to response and shape of CR function
- Some concern about confounding/effect modification (season, weather, co-pollutants) and exposure assessment
- Study results not fully consistent

Studies provide evidence of associations between ozone and:

- Respiratory hospital admissions for children < 2 and all ages combined
- Emergency room visits, particularly for asthma
- School absences and respiratory symptoms
- New onset of asthma (with exercise)
- Long term exposure and lung function
- Mortality from acute, and possibly chronic, summertime exposure

Basis for OEHHA's Health-Based Recommendation

Retain the current 1-hr standard of 0.09 ppm

- Chamber studies report effects of lung function and symptoms effects at 0.12 ppm
- Epidemiological studies suggest adverse effects below 0.12 ppm
- Epidemiological studies on ER visits suggest a lowest effect level in the range of 0.075 to 0.11 ppm

Basis for 1-hr (cont.)

- Provides additional protection against airways inflammation
- Protects against possible effects of peak exposure for certain subgroups
- Includes a safety margin to protect children and other susceptible groups
- Protects against peaks in areas that may meet federal 8-hr standard of 0.08 but still have relatively high 1-hr concentrations.

Basis for OEHHA's Health-Based Recommendation

Establish an 8-hr standard of 0.070 ppm

- Chamber studies report symptoms, lung function changes, and airway responsiveness effects at 0.08 ppm
- Some individuals exhibited large changes with 6.6 hr exposure to 0.08 ppm
- Epi studies suggest adverse effects at 8-hr concentrations less than 0.08 ppm

Basis for 8-hr (cont.)

- Studies on ER visits suggest a lowest effect level in the range of 0.065 to 0.09 ppm
- Includes a safety margin for highly responsive individuals, children and other susceptible groups
- Adds protection in areas with long, low peaks (i.e., some areas that may meet 0.09 1-hr may still have high 8-hr)
- Adds protection against long-term (year or more) exposure

Findings on Infants and Children Under SB 25

- No evidence that children respond to acute exposures at lower O_3 concentrations than adults
- Exposure patterns:
  - Frequent high exposures due to outdoor activity
  - Greater exposure per unit lung surface than adults
- Susceptibility: Early exposure may
  - Affect lung development
  - Reduce lung function
  - Induce asthma

Findings on Infants and Children (cont.)

- No evidence for interactions between pollutants
- Adverse health outcomes reported include:
  - asthma exacerbation and ER visits
  - hospital admissions
  - school loss
  - upper and lower respiratory symptoms
  - possible onset of asthma
  - decreased lung function in young adults raised in high ozone areas

Annual Public Health Benefits Associated With Attainment of the Proposed Standards

- 640 premature deaths
- 3,800 hospitalizations for respiratory diseases
- 130 emergency room visits for asthma for children under 18 years of age
- 3.3 million school absences among children for ages 5 to 17 years of age
- 2.6 million minor restricted activity days for adults above 18 years of age

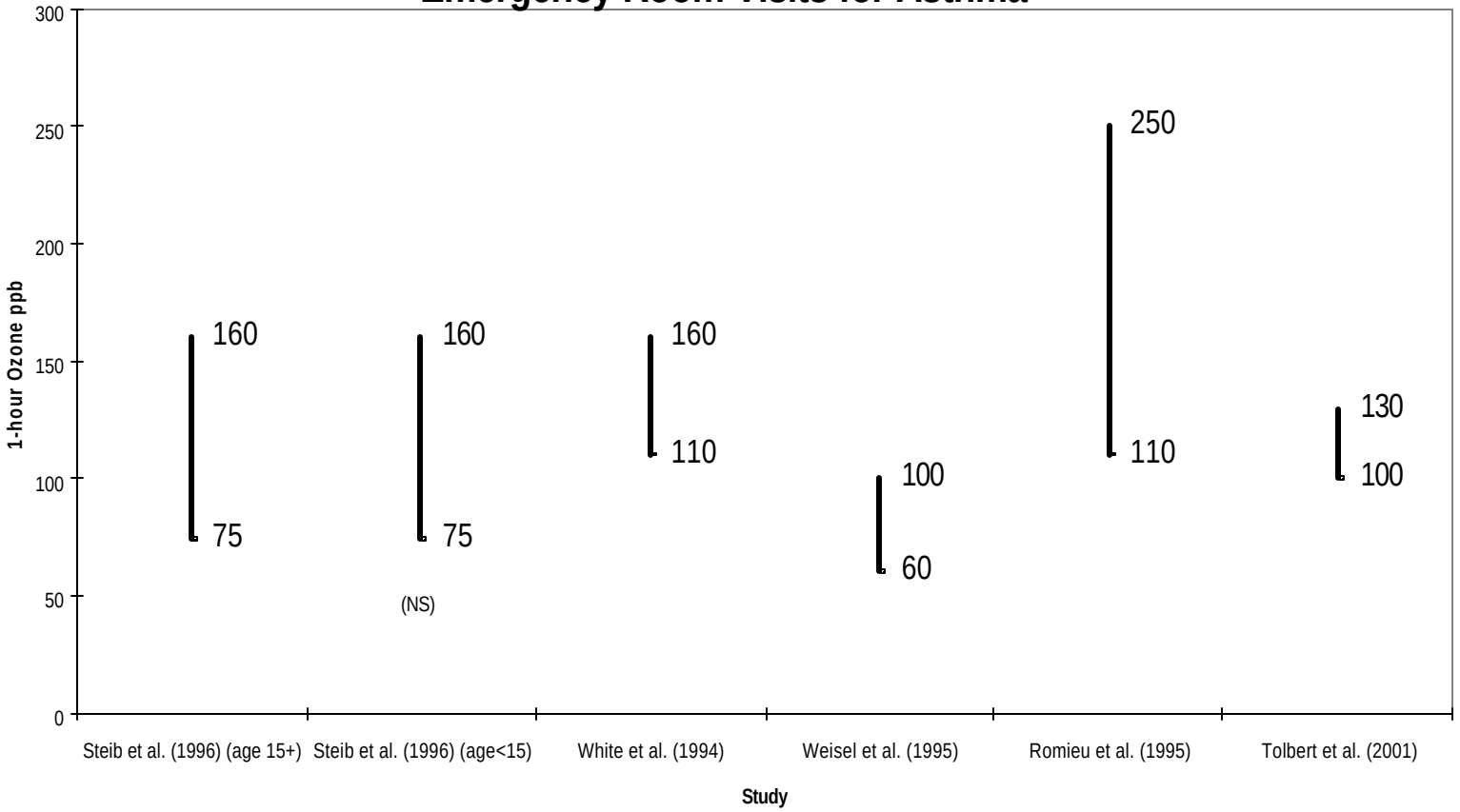
Summary:
Draft Staff Recommendation

- Retain ozone as the pollutant indicator
- Establish a new 8-hr standard of 0.070 ppm, not to be exceeded
- Retain the current 1-hr standard of 0.09 ppm, not to be exceeded
- Retain the UV monitoring method

Some Aspects of Epidemiological Studies

- Wide range of ozone concentrations
- Recent increase in studies published
- Model sophistication appears to increase effect size
- No clear threshold indicated

Intervals of 1-hr Ozone Indicating Likely Effect Levels for Emergency Room Visits for Asthma



Quantifying the Health Benefits of Reducing Ozone Exposure

As in previous efforts, the estimated impact on health is the product of:

- Changes in ozone concentrations
- Population exposed
- Baseline incidence of health outcomes
- % change in health outcome per unit increase in ozone based on evidence from epi studies

Determining Changes in Ozone Concentrations

- Compare State design value (or EPDC) versus standard for each air basin to determine percent rollback
- Apply percent rollback to daily ozone values at all sites within each basin
- Assumes all areas in given basin will be reduced proportionately

Determining Population Exposed

- County population equally apportioned among the number of monitoring sites in the county
- Used year 2000 census

Baseline Incidence of Adverse Health Outcomes

- Most up-to-date information used for the number of health events per year per unit population, mainly through U.S. EPA
- Sources include:
  - U.S. Center for Disease Control and Prevention
  - National Center for Health Statistics
  - National Ambulatory Medical Care Survey
  - School absences: based on Hall et al. (2003)
  - Minor Restricted Activity Days: based on Ostro (1987)

Concentration-Response Functions

- CR functions relate the percent change in adverse health outcome per unit increase in ozone
- CR functions derived from meta-analysis of epidemiological studies
- Assumes effects can occur at levels below the standard, but within the range of ozone reported in epi studies:
  - down to natural background level of 0.04 ppm for most endpoints
  - down to 0.075 ppm (1-hour) or 0.056 ppm (8-hour) for ER visits

Changes in Adverse Health Outcomes

- For each day in years 2001-2003, effect changes was calculated at each site using the CR functions
- Daily changes were summed over each year across all sites
- The average of three annual effect changes was presented as annual benefit of reducing ozone exposure for each health endpoint

Uncertainties and Limitations

- Limited literature
- Uncertainty in ß is reflected in confidence intervals
- Potential confounding factors: weather, co-pollutants, bioaerosols
- Effect threshold: bulk of benefits occur at levels below proposed standards
- Not all effects can be quantified
- Baseline incidence rates may change over time
- Exposure based on existing network may not be representative of general population exposure